

# EXHIBIT 1

Document

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**THE WALL STREET JOURNAL.****Missing a Beat: How a Breakthrough Quickly Broke Down For Johnson & Johnson — Its Stent Device Transformed Cardiac Care, Then Left A Big Opening for Rivals — 'Getting Kicked in the Shins'***Wall Street Journal*; New York; Sep 18, 1998; By Ron Winslow;

**Edition:** Eastern edition  
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**Subject Terms:** Medical equipment  
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 Product development  
 Strategic planning  
 Sales  
 Financial performance  
 Cardiovascular disease

**Companies:** Johnson & Johnson**Abstract:**

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*Now, as the annual U.S. market for stents surges past \$1 billion, Guidant shares more than 80% of it with yet another competitor, Arterial Vascular Engineering Inc. A fourth maker, Boston Scientific Corp., just won regulatory approval to enter the market. J&J's stent sales, meanwhile, are in free fall. Glenn Reicin, a Morgan Stanley analyst who pegged J&J's market share at 91% at the end of 1996, expects it to plummet to 8% by the end of this year.*

*"Their stent changed cardiology and the treatment of coronary-artery disease forever," says Eric Topol, chairman of cardiology at the Cleveland Clinic, one of the world's leading heart centers. But "they didn't sustain the technology. They left the door open for the other manufacturers to come on the market with better designs."*

**Full Text:***Copyright Dow Jones & Company Inc Sep 18, 1998*

Four years ago, Johnson & Johnson sparked a revolution in the treatment of coronary-artery disease with a new medical device called a stent.

Few devices have yielded such an immediate eye-popping bonanza for their manufacturer. Doctors rushed to use the tiny metal scaffold to prop open obstructed heart vessels. In just 37 months, the New Brunswick, N.J., health-care giant tallied more than \$1 billion of stent sales and garnered more than 90% of a remarkably profitable U.S. market.

Then last fall, Guidant Corp. launched a competing stent in the U.S. "Within 45 days, we had gained a 70% market position," says Ronald W. Dollens, Guidant's president and chief executive officer. J.P. Morgan analyst Michael Weinstein characterizes the shift as "the most dramatic transfer of wealth between two companies in medical-device history."

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"They were acknowledged to be the technology leader and to have an almost insurmountable lead," says David Fish, director of interventional cardiology research and education at the renowned Texas Heart Institute in Houston. "Somewhere along the line, they didn't anticipate the temperament of the marketplace."

How J&J, the revered marketer of baby powder, Band-Aids and Tylenol, won and lost the hottest medical-device market of the 1990s points up both the rewards of innovation and the perils of monopoly. Interviews with dozens of cardiologists and other industry insiders suggest that after doing almost everything right to get a breakthrough product approved by regulators, J&J did almost everything wrong to protect its franchise.

"Their stent changed cardiology and the treatment of coronary-artery disease forever," says Eric Topol, chairman of cardiology at the Cleveland Clinic, one of the world's leading heart centers. But "they didn't sustain the technology. They left the door open for the other manufacturers to come on the market with better designs."

Indeed, J&J was slow to develop next-generation versions of its technology, and left the impression among top doctors that it was banking on a strong patent to protect its product from competition. What appeared to be a master stroke to broaden its cardiology line -- its \$1.8 billion acquisition of angioplasty-balloon maker Cordis Corp. -- also devolved into a culture clash that stalled product development and led to an exodus of Cordis talent.

Compounding these missteps, J&J angered many key customers with rigid pricing for its \$1,595 device, balking at discounts even for accounts that purchased more than \$1 million of stents a year. For hospitals' catheterization labs, where stent procedures are done, this exacerbated a budget-busting investment at a time when managed care and the national debate on health costs were putting enormous pressure on hospitals.

With no comparable stent options, many doctors felt gouged. The result was an astonishing pool of resentment among cardiology's highest-profile practices, which came back to haunt J&J as soon as new stents arrived in the U.S. last fall.

"Everybody was at our throats" over costs, says Louis McKeever, director of the catheterization lab at Loyola University Hospital in Chicago. "We were trying to do the best we could for our patients. I expected J&J should have participated in the effort."

J&J acknowledges that it didn't move fast enough to advance its device and that it misread a clientele with whom it hadn't previously done business. It says its  $\diamond$  Cordis acquisition was troubled by factors typical of the initial stages of mergers. But it staunchly defends its pricing strategy. The main problem, J&J maintains, was that insurers initially refused to reimburse hospitals for any costs beyond the standard angioplasty rate. The company mounted an aggressive and ultimately successful campaign to win higher insurance coverage.

In any event, J&J says it now has a full pipeline of new products that will be competitive in what has become a crowded market. "We know we're getting kicked in the shins right now," says Robert W. Croce, a J&J group chairman in charge of the Cordis business line. "But we're doing a lot to get back in

the race."

This is in a market that revolves around a tiny metal-mesh tube no thicker than a pencil lead, crimped on a tiny balloon that is threaded into the heart's arteries. At a blockage site, the balloon is inflated to deploy the stent, creating a scaffold resembling a ballpoint-pen spring that remains to keep the vessel open after the balloon is withdrawn.

When J&J introduced its device, known as the Palmaz-Schatz stent, in August 1994, cardiologists had long been frustrated by a major drawback in balloon angioplasty, their flagship procedure: the tendency of arteries to reclose or reclog after being opened with a balloon. In up to 5% of balloon-only cases, the vessel snaps shut abruptly within minutes or a few days -- a life-threatening event that often requires a risky emergency coronary-artery bypass operation. In addition, about 30% of the 400,000 angioplasties done annually in the U.S. fail within six months -- due to a renarrowing known as restenosis -- leading to further treatment.

J&J's stent all but eliminated the abrupt-closure problem, and cut the longer-term failure rate in half. As doctors leapt to embrace it, they tipped their hats to the company for its seven-year effort to get the device to market: It had persevered in the face of regulatory skepticism about safety and the failure of a competing stent that caused deaths. "The original J&J design had a very good track record that was honorably and painstakingly acquired," says the Texas Heart Institute's Dr. Fish. "J&J absolutely developed this market," adds Mr. Dollens of Guidant. "They took the early risks of whether this therapy would work at all."

And they reaped the rewards. In the first year after the U.S. launch, an estimated 100,000 patients received stents amid a frenzy of enthusiasm that promised soaring future sales. With gross profit margins estimated at more than 80%, analysts figured that a product that, at its peak, provided about 4% of J&J's annual revenue, accounted for about 8% of its bottom line. Moreover, competitors had to mount trials to show their products were as good as the Palmaz-Schatz standard before they could win regulatory approval.

But like most first-generation medical devices, the Palmaz-Schatz has limitations. Its width and rigidity make it difficult to use in narrow or sometimes gnarled coronary arteries of heart patients. It isn't easily visible in the X-ray pictures doctors use to guide them to the site of a blockage. And it comes in just one length -- about five-eighths of an inch -- requiring the use of two more stents to treat longer obstructions.

At first, these shortcomings were small annoyances. But the nation's 6,000 interventional cardiologists soon became impatient. This small cadre of physicians are medical-technology junkies who thrive on the latest and best products, who often work closely with manufacturers to improve existing devices and test new ones.

Since J&J was a newcomer to the catheterization lab, some doctors suspected the stent was a one-hit wonder. Others sensed that J&J was behaving more like a drug company, for which rapid product cycles are less important. "As a physician, I expect products to change every year," says Martin B. Leon, chief executive of the Cardiology Research Foundation at Washington Hospital Center, Washington, D.C., and a consultant to J&J on the device. "As a corporation, they couldn't understand that."

Moreover, by early 1996, more-advanced stents from Guidant, AVE and other companies were available in Europe, where regulatory hurdles are lower than in the U.S. This led to an epidemic of stent envy among U.S. cardiologists.

J&J's Mr. Croce says the small unit that developed the stent was so focused on getting it to market, and meeting enormous demand, that it devoted little time or resources to the next generation. Once that effort began, he says, developers spent too much time modifying the original and didn't pay enough attention to ease-of-use features that cardiologists wanted.

The other big flaw in J&J's stent, according to cardiologists and hospital administrators, was its price. The stent's popularity provoked an explosion in unexpected costs in catheterization labs, typically crucial hospital profit centers. St. Joseph's Hospital in Atlanta, for instance, spent \$2 million for stents in 1995 after buying hardly any the year before, one doctor says. Stent-related technology added sharply to the cost of a routine angioplasty procedure. But insurers generally continued to reimburse hospitals at regular angioplasty rates.

Administrators and cardiologists at high-volume hospitals asked J&J for a break. At Our Lady of Lourdes Hospital in Lafayette, La., Stephanie Mayeaux, director of cardiovascular procedures, first sought a discount based on the number of stents her hospital used. Rebuffed, she pooled the purchases of a three-hospital system. Still no deal. Finally, she tried to leverage the buying power of a 300-hospital purchasing group. "J&J did not bend," she says. Major programs in Washington, D.C., Minneapolis, Chicago, New York and elsewhere were similarly frustrated.

J&J also alienated the prestigious Cleveland Clinic. "In their dealings with catheterization labs, there was a very strong sense of arrogance," the clinic's Dr. Topol says. When he and his associates sought better rates, they say, J&J officials suggested they could help doctors design "care tracks" to make the procedure more efficient. "They were implying that we didn't know how to manage our patient population," recalls Mary Heisler, manager of the catheterization lab.

J&J says the stent was a bargain in the U.S. compared to the \$2,400 initially charged in Europe, and the \$3,500 sticker price in Japan. And it was only \$200 more than another stent on the U.S. market for a very narrow application. "We were never price-gouging," says Marvin Woodall, who headed the unit that brought the stent to the market and is now an international vice president for J&J. Today, the stent sells for about \$1,000 in Europe, where competition has driven prices down, and about \$3,000 in Japan.

The company says it has been vindicated by its competitors. Comparable stents from Guidant, AVE and Boston Scientific are similarly priced. And Mr. Croce says J&J eventually gave discounts to a dozen high-volume centers, including the Cleveland Clinic. "Doctors have short memories," he says.

When J&J launched its hostile bid to acquire Cordis late in 1995, many heart doctors believed both their technology and economic concerns would be addressed. Cordis had built a \$500 million-a-year business in equipment used in angioplasty, including a high-pressure balloon favored by many cardiologists using the stent. Combining the companies, doctors felt, would yield new products and increase prospects for package pricing.

But the anticipated synergy didn't develop. Former Cordis insiders say that J&J's top-down culture clashed with a more entrepreneurial approach that characterized Cordis under Robert C. Strauss, its chief executive officer. And though Cordis was much more experienced with catheterization-lab technology and in dealing with cardiologists, its managers felt that J&J's views prevailed on essentially all early decisions.

A stent that Cordis was about to launch in Europe was shelved. Efforts to combine J&J's stent with the high-pressure balloon foundered. Cordis's "core teams," adept at rapid product development by integrating marketing, R&D and manufacturing operations around specific business lines, were replaced

by a more traditional structure that had such functions reporting to separate managers.

The new Cordis didn't come to market with a significant new product until last January-nearly two years after the acquisition. Called the Crown stent, it was significantly outmatched by Guidant and AVE products when it was launched.

"People always underestimate what it takes to put two companies together," says J&J's Mr. Croce, but he defends the acquisition. "We're past a lot of the troubles," he says. But he readily concedes that the combination of J&J's inexperience with the cardiology industry and struggles with the Cordis integration were big factors in a "lag time" in product development.

By early 1997, the patience of many doctors with the Palmaz-Schatz stent was wearing thin. At the Cleveland Clinic, for instance, Dr. Topol became particularly frustrated after complications during an angioplasty procedure forced one of his patients to undergo an emergency bypass. "Had we had access to new stent designs, that would have turned things around" for her, he says. (The patient recovered.)

Top cardiologists, including Dr. Topol, urged the FDA to expedite approval of competing stents. Last October, the FDA cleared Guidant's Multi-link stent just 112 days after the company filed its application; by the end of December, it accepted AVE's stent. "These new stents are so much hands-down better," Dr. Topol says. "We needed them."

J&J was powerless to prevent the resulting rout. Discounts for what was perceived as inferior technology wouldn't work, and doctors weren't interested in J&J's argument that the Palmaz-Schatz stent had a proven track record.

Meantime, J&J's efforts on reimbursement began to bear fruit. Mr. Woodall headed an intense project to persuade insurers that they were underpaying for stent procedures. "They were benefiting because their patients weren't coming back for second and third angioplasties," Mr. Woodall says. The company's analysis of public data on 200,000 Medicare patients convinced Medicare officials to increase stent reimbursement by \$2,300, or 26%.

The new rate became effective last Oct. 1 -- just in time to benefit J&J's competitors. The next day, Guidant's stent hit the market at a list price no cheaper than J&J's device.

Now J&J has several new products in clinical trials, including the "miniCrown," for smaller arteries and a product intended to improve on the stent's track record in preventing restenosis. By the middle of next year, it expects to launch the Cross Flex LC, a "slick" stent, say doctors who have used it in clinical trials. That endorsement comes with irony for J&J -- the device is patterned after the old Cordis design the company rejected.

Mr. Croce says these products should convince skeptics the company is committed to the cardiology market. He says the only way the company can put to rest the resentment among key customers is with better products. "You can't sell everybody," he says. "But I think we have a decent following. When our technology matches up, they'll come back."

But Guidant, AVE and Boston Scientific are advancing their already-preferred devices as well. James J. Ferguson III, associate director of cardiology research at Texas Heart Institute, says J&J's road back to prominence in the market it created won't be easy. "J&J went out and poisoned the well," he says. "They have a couple of nice products in the pipeline, but they also have a huge backlog of ill will that is going to take a while to dissipate."

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Credit: Staff Reporter of The Wall Street Journal

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## Washington Wire

A Special Weekly Report From  
The Wall Street Journal's  
Capital Bureau

**DEMOCRATS SCRAMBLE** for ways to  
ride out the Clinton sex-scandal storm.

Senate Democrats mull pushing for a  
quick censure vote, even if it doesn't end  
impeachment debate.

The goal: to help sen-  
ators up for re-elec-  
tion distance them-  
selves from Clinton's  
troubles. In a Wall  
Street Journal/NBC  
News poll, for the  
first time in Clinton's  
presidency as many  
Americans (43%) have negative feelings  
about him as have positive ones (40%).

In the House, Democratic strategists  
gripe that Clinton's new damage-control  
team is heavy with former Senate hands.  
White House aides and Clinton lawyers fight  
over the role of lawyer David Kendall in  
handling Clinton's defense to the looming  
House inquiry. Some aides blame Kendall's  
aggressive lawyering for political setbacks.

The videotape of Clinton's grand-jury  
testimony opens with prosecutors asking  
the president his understanding of the  
meaning of the oath to tell "the whole  
truth."

**CLINTON CLINGS** to the economy as an  
anchor, but some worries rise.

A sky-high 86% of Americans are satis-  
fied with the U.S. economy. "It is the  
economy and little else on which the Clinton  
presidency hinges," say Democrat Peter  
Hart and Republican Robert Teeter, who  
ran the poll. Stock turmoil has little impact,  
though 45% expect the Dow Jones Industrial  
Average to drop to 7,000 by year end, while  
35% see a rise to 9,000.

But a growing minority — 31% — sees a  
recession in the next 12 months; only 25%  
had a similar view as the economy slid  
into recession in 1990. The Asian financial  
crisis is cited as the biggest threat, much  
more so than in July's poll. Fed officials say  
the current quarter, ending Sept. 30, looks  
good, but they are less confident about next  
year.

**GORE STRUGGLES** to stave off political  
erosion amid Clinton's scandal woes.

The crisis and continued probes of Gore's  
1996 fund-raising activities "appear to be  
taking their toll on his standing," say  
pollsters Hart and Teeter. Two-thirds of  
Americans are only somewhat or not at all  
confident in Gore's ability to lead the coun-  
try. But Americans by 61% to 37% say he  
is ready to assume duties as president if  
necessary.

Texas Gov. Bush's lead over Gore in a

THE WALL  
STREET  
JOURNAL/  
NBC NEWS  
POLL

## Missing a Beat

How a Breakthrough  
Quickly Broke Down  
For Johnson & Johnson

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'Getting Kicked in the Shins'

By RON WINSLOW

Staff Reporter of THE WALL STREET JOURNAL  
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**Sharing the Market**

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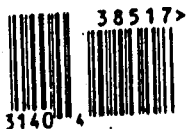
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Texas Gov. Bush's lead over Gore in a  
potential 2000 matchup rises to 10 percent-  
age points from three in April. But Gore is  
dominant among Democrats polled in the  
race for his party's nomination. The "best  
way for him to define himself" is to  
win primaries, not to have replaced Clinton  
early, says Simon Rosenberg of the New  
Democrat Network.

Americans by 57% to 27% still would  
prefer Clinton over Gore as president.

CLINTON'S CLOUT will be tested in a  
Senate vote today to ban partial-birth abor-  
tion; the GOP needs only a few more  
Democrats to get enough votes to override a  
certain Clinton veto. Americans by 42% to  
30% say they would be more likely to support  
a candidate who favors banning such abor-  
tions.

NYET! Russian hopes for more aid from  
the U.S. Congress are undermined by Yel-  
tsin's choice of new Prime Minister Yevgeny  
Primakov, who is seen as a defender of  
Saddam Hussein. In the poll, Americans by  
52% to 35% don't think the U.S. should  
provide financial aid to Russia.

HIGH-TECH HELP: Clinton adviser  
Gene Sperling meets with GOP Sen. Abra-  
ham to indicate a willingness to compromise  
on a bill pushed by Silicon Valley to allow  
more work visas for skilled foreigners. Clin-  
ton is slated for a fund-raiser this month at  
the home of Silicon Valley venture-capitalist  
John Doerr.

SCANDAL DIVERSIONS disrupt legisla-  
tion. A White House plan to boost security at  
U.S. embassies may be a budget-light  
casualty. Senate political jousting muddles  
bankruptcy overhaul, a GOP priority. In the  
poll, Americans by 61% to 28% approve of  
the job Congress is doing.

HOPES RISE that Pakistan will sign the  
nuclear-test-ban treaty.

Clinton will press the issue when he  
meets with Pakistan Prime Minister Sharif  
at the U.N.'s annual meeting next week.  
An agreement would be the first big break-  
through since Pakistan and India set off  
nuclear-weapons tests last May. U.S. offi-  
cials say Pakistan wants IMF aid and assur-  
ances that economic sanctions imposed after  
the blasts will be lifted.

On other issues, Clinton in his speech  
Monday to the General Assembly will focus  
on terrorism. He will argue that combating  
terrorists is every nation's problem, not just  
a face-off between the U.S. and Islam.  
Clinton will also press economic reform on  
Japan's Prime Minister Obuchi.

The president will argue for more  
forceful action in Kosovo in a meeting  
with Italy's Prodi.

MINOR MEMOS: Among the "Starr"  
reports listed for those seeking the Starr  
Report on Clinton at the Internet's Ama-  
zon.com is, "The Starr-Weiner Report on  
Sex and Sexuality in the Mature Years." ...  
Gore, responding in Seattle to GOP Sen.  
Gorton's attacks on the Endangered Species  
Act, says, "He must have been bitten by a  
squirrel as a child."

—RONALD G. SHAFER

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mous pressure on hospitals.

#### A Pool of Resentment

With no comparable stent options,  
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market. "We know we're getting kicked in  
the shins right now," says Robert W.  
Cruce, a J&J group chairman in charge of  
the Cordis business line. "But we're doing  
a lot to get back in the race."

This is in a market that revolves around  
a tiny metal-mesh tube no thicker than a  
Pense Turn to Page A5, Column 1

8

1998

# Missing a Beat: How a Breakthrough Broke

*Continued From First Page*

pencil lead, crimped on a tiny balloon that is threaded into the heart's arteries. At a blockage site, the balloon is inflated to deploy the stent, creating a scaffold resembling a ballpoint-pen spring that remains to keep the vessel open after the balloon is withdrawn.

When J&J introduced its device, known as the Palmaz-Schatz stent, in August 1994, cardiologists had long been frustrated by a major drawback in balloon angioplasty, their flagship procedure: the tendency of arteries to reclose or relog after being opened with a balloon. In up to 5% of balloon-only cases, the vessel snaps shut abruptly within minutes or a few days—a life-threatening event that often requires a risky emergency coronary-artery bypass operation. In addition, about 30% of the 400,000 angioplasties done annually in the U.S. fail within six months—due to a re-narrowing known as restenosis—leading to further treatment.

J&J's stent all but eliminated the abrupt-closure problem, and cut the longer-term failure rate in half. As doctors leapt to embrace it, they tipped their hats to the company for its seven-year effort to get the device to market: It had persevered in the face of regulatory skepticism about safety and the failure of a competing stent that caused deaths. "The original J&J design had a very good track record that was honorably and painstakingly acquired," says the Texas Heart Institute's Dr. Fish. "J&J absolutely developed this market," adds Mr. Dollens of Guidant. "They took the early risks of whether this therapy would work at all."

And they reaped the rewards. In the first year after the U.S. launch, an estimated 100,000 patients received stents amid a frenzy of enthusiasm that promised soaring future sales. With gross profit margins estimated at more than 80%, analysts figured that a product that, at its peak, provided about 4% of J&J's annual revenue, accounted for about 7% of its bottom line. Moreover, competitors had to mount trials to show their products were as good as the Palmaz-Schatz standard before they could win regulatory approval.

But like most first-generation medical devices, the Palmaz-Schatz has limitations. Its width and rigidity make it difficult to use in narrow or sometimes gnarled coronary arteries of heart patients. It isn't easily visible in the X-ray pictures doctors use to guide them to the site of a blockage. And it comes in just one length—about five

catheterization labs, there was a very strong sense of arrogance," the clinic's Dr. Topol says. When he and his associates sought better rates, they say, J&J officials suggested they could help doctors design "care tracks" to make the procedure more efficient. "They were implying that we didn't know how to manage our patient population," recalls Mary Heisler, manager of the catheterization lab.

J&J says the stent was a bargain in the U.S., compared to the \$2,400 initially charged in Europe, and the \$3,500 sticker price in Japan. And it was only \$200 more than another stent on the U.S. market for a very narrow application. "We were never price-gouging," says Marvin Woodall, who headed the unit that brought the stent to the market and is now an international vice president for J&J. Today, the stent sells for about \$1,000 in Europe, where competition has driven prices down, and about \$3,000 in Japan.

The company says it has been vindicated by its competitors. Comparable stents from Guidant, AVE and Boston Scientific are similarly priced. And Mr. Croce says J&J eventually gave discounts to a dozen high-volume centers, including the Cleveland Clinic. "Doctors have short memories," he says.

When J&J launched its hostile bid to acquire Cordis late in 1995, many heart doctors believed both their technology and economic concerns would be addressed. Cordis had built a \$500 million-a-year business in equipment used in angioplasty, including a high-pressure balloon favored by many cardiologists using the stent. Combining the companies, doctors felt, would yield new products and increase prospects for package pricing.

## Culture Clash

But the anticipated synergy didn't develop. Former Cordis insiders say that J&J's top-down culture clashed with a more entrepreneurial approach that characterized Cordis under Robert C. Strauss, its chief executive officer. And though Cordis was much more experienced with catheterization-lab technology and in dealing with cardiologists, its managers felt that J&J's views prevailed on essentially all early decisions.

A stent that Cordis was about to launch in Europe was shelved. Efforts to combine J&J's stent with the high-pressure balloon foundered. Cordis's "core teams," adept at rapid product development by integrating marketing, R&D and manufacturing operations around specific business lines, were

"People always underestimate what takes to put two companies together," says J&J's Mr. Croce, but he defends the acquisition. "We've past a lot of the troubles," he says. But he readily concedes that a combination of J&J's inexperience with the cardiology industry and struggles with the Cordis integration were big factors in "lag time" in product development.

By early 1997, the patience of many doctors with the Palmaz-Schatz stent was wearing thin. At the Cleveland Clinic, for instance, Dr. Topol became particularly frustrated after complications during angioplasty procedure forced one of his patients to undergo an emergency bypass. "Had we had access to new stent design that would have turned things around" for her, he says. (The patient recovered.)

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At first, these shortcomings were small annoyances. But the nation's 6,000 interventional cardiologists soon became impatient. This small cadre of physicians are medical-technology junkies who thrive on the latest and best products, who often work closely with manufacturers to improve existing devices and test new ones.

Since J&J was a newcomer to the catheterization lab, some doctors suspected the stent was a one-hit wonder. Others sensed that J&J was behaving more like a drug company, for which rapid product cycles are less important. "As a physician, I expect products to change every year," says Martin B. Leon, chief executive of the Cardiology Research Foundation at Washington Hospital Center, Washington, D.C., and a consultant to J&J on the device. "As a corporation, they couldn't understand that."

#### Stent Envy

Moreover, by early 1996, more-advanced stents from Guidant, AVE and other companies were available in Europe, where regulatory hurdles are lower than in the U.S. This led to an epidemic of stent envy among U.S. cardiologists.

J&J's Mr. Croce says the small unit that developed the stent was so focused on getting it to market, and meeting enormous demand, that it devoted little time or resources to the next generation. Once that effort began, he says, developers spent too much time modifying the original and didn't pay enough attention to ease-of-use features that cardiologists wanted.

The other big flaw in J&J's stent, according to cardiologists and hospital administrators, was its price. The stent's popularity provoked an explosion in unexpected costs in catheterization labs, typically crucial hospital profit centers. St. Joseph's Hospital in Atlanta, for instance, spent \$2 million for stents in 1995 after buy-

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The new Cordis didn't come to market with a significant new product until last January—nearly two years after the acquisition. Called the Crown stent, it was significantly outmatched by Guidant and AVE products when it was launched.

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heights of an inch—requiring the use of two more stents to treat longer obstructions.

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The other big flaw in J&J's stent, according to cardiologists and hospital administrators, was its price. The stent's popularity provoked an explosion in unexpected costs in catheterization labs, typically crucial hospital profit centers. St. Joseph's Hospital in Atlanta, for instance, spent \$2 million for stents in 1995 after buying hardly any the year before, one doctor says. Stent-related technology added sharply to the cost of a routine angioplasty procedure. But insurers generally continued to reimburse hospitals at regular angioplasty rates.

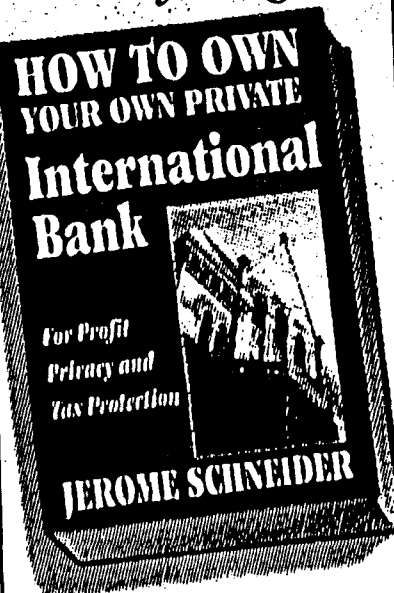
Administrators and cardiologists at high-volume hospitals asked J&J for a break. At Our Lady of Lourdes Hospital in Lafayette, La., Stephanie Mayeux, director of cardiovascular procedures, first sought a discount based on the number of stents her hospital used. Rebuffed, she pooled the purchases of a three-hospital system. Still no deal. Finally, she tried to leverage the buying power of a 300-hospital purchasing group. "J&J did not bend," she says. Major programs in Washington, D.C., Minneapolis, Chicago, New York and elsewhere were similarly frustrated.

J&J also alienated the prestigious Cleveland Clinic. "In their dealings with

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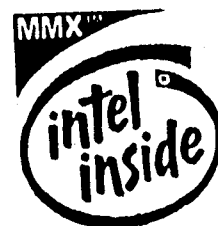
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# Through Broke Down

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By early 1997, the patience of many doctors with the Palmaz-Schatz stent was wearing thin. At the Cleveland Clinic, for instance, Dr. Topol became particularly frustrated after complications during an angioplasty procedure forced one of his patients to undergo an emergency bypass. "I had we had access to new stent designs, that would have turned things around" for her, he says. (The patient recovered.)

Top cardiologists, including Dr. Topol, urged the FDA to expedite approval of competing stents. Last October, the FDA cleared Guidant's Multi-link stent just 112 days after the company filed its application; by the end of December, it accepted AVE's stent. "These new stents are so much hands-down better," Dr. Topol says. "We needed them."

J&J was powerless to prevent the resuiting rout. Discounts for what was perceived as inferior technology wouldn't work, and doctors weren't interested in J&J's argument that the Palmaz-Schatz stent had a proven track record.

Meantime, J&J's efforts on reimbursement began to bear fruit. Mr. Woodall headed an intense project to persuade insurers that they were underpaying for

stent procedures. "They were benefiting because their patients weren't coming back for second and third angioplasties," Mr. Woodall says. The company's analysis of public data on 200,000 Medicare patients convinced Medicare officials to increase stent reimbursement by \$2,300, or 26%.

## The Next Wave

The new rate became effective last Oct. 1—just in time to benefit J&J's competitors. The next day, Guidant's stent hit the market at a list price no cheaper than J&J's device.

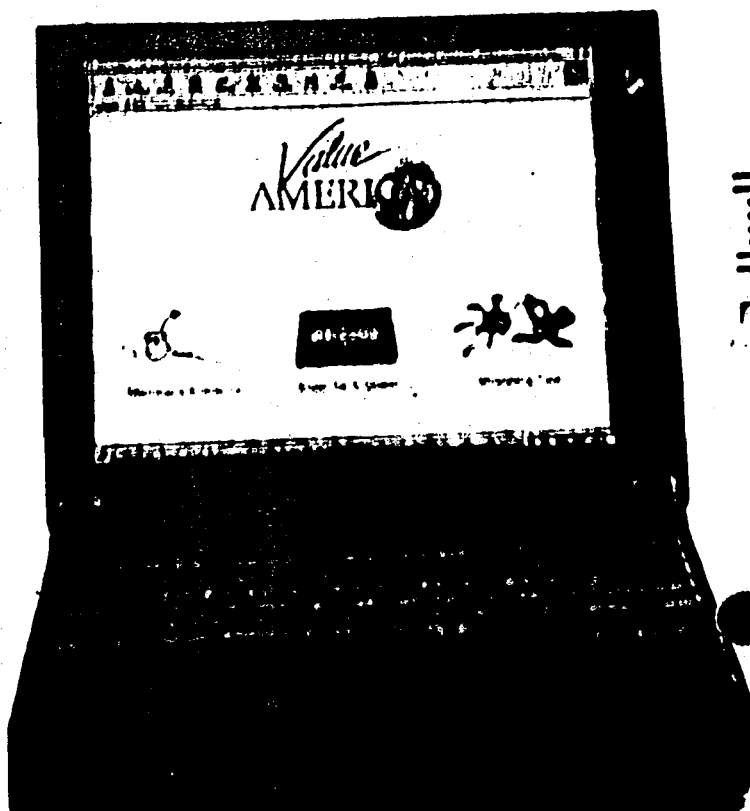
Now J&J has several new products in clinical trials, including the "mini-Crown," for smaller arteries and a product intended to improve on the stent's track record in preventing restenosis. By the middle of next year, it expects to launch the Cross Flex LC, a "slick" stent, say doctors who have used it in clinical trials. That endorsement comes with irony for J&J—

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## OWN

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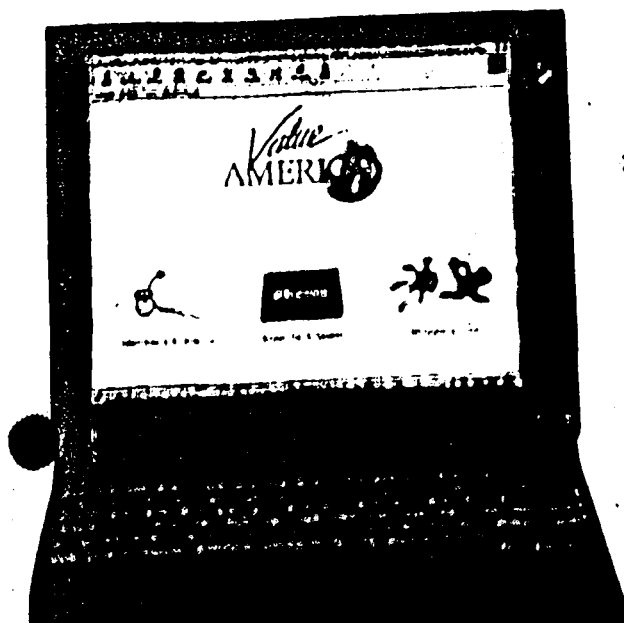
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the device is patterned after the old Cordis design the company rejected.

Mr. Croce says these products should convince skeptics the company is committed to the cardiology market. He says the only way the company can put to rest the resentment among key customers is with better products. "You can't sell everybody," he says. "But I think we have a decent following. When our technology matches up, they'll come back."

But Guidant, AVE and Boston Scientific are advancing their already-preferred devices as well. James J. Ferguson III, associate director of cardiology research at Texas Heart Institute, says J&J's road back to prominence in the market it created won't be easy. "J&J went out and poisoned the well," he says. "They have a couple of nice products in the pipeline, but they also have a huge backlog of ill will that is going to take a while to dissipate."

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# EXHIBIT 2

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and on behalf of ENDOVASCULAR  
SUPPORT SYSTEMS, INC., and  
BENITO HIDALGO, Individually  
and on behalf of ENDOVASCULAR  
SUPPORT SYSTEMS, INC., a  
California Corporation,

Plaintiffs,

vs.

ARTERIAL VASCULAR ENGINEERING,  
INC., a Delaware Corporation,  
SIMON H. STERTZER, M.D., GERALD  
DORROS, M.D., JOHN MILLER and  
BRADLY JENDERSEE,

Defendants.

NO. 96-05323-M

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BRADLY A. JENDERSEE

Monday, July 7, 1997

VOLUME I  
Pages 1-231

Attorneys' Eyes Only  
Pages 153-158, 175-176  
Under Separate Cover

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1 commercializing the stent on the market. So that  
2 may have been a factor. I don't recall  
3 specifically.

4 Q. And the deal with the Japanese  
5 distributor that you just mentioned, that was the  
6 deal that was entered into in December of 1993; is  
7 that correct?

8 A. That's correct.

9 Q. And you're saying that the deal with the  
10 Japanese distributor on balloon catheters that was  
11 entered in December of 1993 may have come into play  
12 in selecting the number of 3,600 shares to  
13 Dr. Dorros, as opposed to some other number that  
14 was less than 20,000?

15 A. It's possible that at that time, based  
16 on -- I believe we had shipped over five million  
17 dollars of balloon product to our Japanese  
18 distributor sometime in mid to late 1994, and based  
19 on the fact that the MicroStent PL was not a viable  
20 product and was not a product that we could  
21 commercialize and we essentially had to go back to  
22 the drawing board with respect to any future  
23 designs to effectively create any opportunity in  
24 the coronary stent market, that it's possible that  
25 that would have been a consideration for the

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# EXHIBIT 3

**AVE: Arterial Vascular Engineering, Inc.**  
Chapter One

**GENERAL ORIENTATION AND INTRODUCTION TO ARTERIAL VASCULAR  
ENGINEERING AND PRODUCTS**

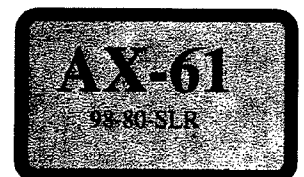
**OBJECTIVES**

At the end of this training module the participant will be expected to:

1. Briefly summarize the history of Arterial Vascular Engineering (aka. AVE ).
2. Understand the developmental history of AVE PTCA Balloon Catheters, the Coronary Micro Stent™ and GFX™ stent Systems and the peripheral vascular Bridge™ Stent Systems.
3. Briefly describe the PTCA balloon and MicroStent manufacturing process.

This will be accomplished within the following sections:

- Section I: Company History  
Section II: History of the PTCA Balloon and Stent Delivery System(s)  
Development  
Section III: Manufacturing Overview



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**Chapter One**

reach nominal diameter at 6 atms and because of the semi-compliant nature of the balloon material, the balloon will over-expand slightly at higher pressures. (See Figure XXX, Balloon Compliance Chart ).

The balloons are available in a variety of diameters and lengths ranging from 1.5- 4.0 mm diameters and 20- 40mm lengths. Catheter length is 135 cms with a usable catheter length of

A modified version of the AVE PTCA balloons is used as the coronary stent delivery system for the MicroStent II and the GFX.

**B. Early Stent Design and Changes: MicroStent PL and MicroStent I**

At the time of the original stent design, it was not known how the human body would react to placement of a metallic device into an artery (biocompatibility) and how long the stent would be viable. Early researchers had many questions as to metal corrosion due

to the blood-metal interaction as well as how the artery would stand-up to the metal prosthesis rubbing against it. Some researchers felt that the stent would wear a hole through the wall of the artery. The engineering idea behind the design of the original MicroStent was to attempt to design a stent that was flexible, visible and low in metal content (metal to artery wall coverage). With these ideas in mind, development of the MicroStent PL began.

The original stent design was developed by an engineer by the name of Michael Bonneau and is still occasionally referred to as the Bonneau stent. However, the stent is the sole property of AVE.

The MicroStent coronary stent system begins with a solid, continuous 7mm diameter ring of high-quality, medical grade 316L stainless steel. This ring, with a wire thickness of 0.008" and is sinusoidal in design, is then shaped into individual elements or segments to a zig-zag like configuration, known as crowns. The original stent design also consisted of 4-crown elements.

The MicroStent PL was designed as individual 4mm sinusoidal segments mounted onto a balloon delivery system. The stents were available in 4mm segments as either 4mm, 8mm or 12mm. Keeping flexibility in mind, the individual 4mm segments were not connected and were mounted onto a balloon for delivery. In difficult lesion subsets, such

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**AVE: Arterial Vascular Engineering, Inc.**  
Chapter One

as calcified lesions or severe vessel tortuosity, it was reported that the individual stent segments had migrated slightly from the deployment site. This was due largely to the short, 4mm segments as well as due to the fact that the segments were not connected together and placed in situations that allowed for slippage at high pressures. The MicroStent PL was used solely as an investigational device and led the way for further changes and enhancements.

The second stage of stent development, the MicroStent I, consisted of two 4mm segments laser fused together, at the four crowns, to form one 8mm segment.

Two

8mm segments could be mounted onto a balloon to form a 16mm length stent.

However,

once again, the two 8mm segments of the 16mm stent were not fused together giving the angiographic appearance that the stent had broken or separated in the center. The stent was also designed to be compatible with a guiding catheter that had a 0.076" minimum internal diameter.

The AVE MicroStent stent system is a non-sheathed, pre-mounted design. The method of adhering the stent to the PTCA balloon is a proprietary process and very unique.  
XXXX

The early stents had a number of disadvantages or not optimal design features:

1. MicroStent PL

4mm segments:

- a. Does this large area between the metal struts allow plaque material to prolapse through the struts?
- b. Do the unattached 4mm segments move or migrate within the artery/lesion with balloon inflation?

2. MicroStent I

4mm segments joined to form 8mm segments:

In addition to the issues above with the MicroStent PL, there were also additional concerns expressed. Those were:

- a. Angiographic appearance not smooth.
- b. Does the laser fusion weld break?
- c. Is the 8mm segment flexible enough?
- d. Is the wire thickness of .008" too thick if stents have to be overlapped?

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# EXHIBIT 4

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# December 1997

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Degois-Sainz, M.	S311
Douthitt, T.	S112
Esselstein, B.	T120
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Muller, P.	S116
Nayak, V.	S120
Nishimura, M.	S112
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Spaulding, R.	S232

**Finance**

Bartels, S.	S216
Mariani, P.	S216

**Business Development**

Bertonis, J.	S214
Gasson, J.	S214
<div style="background-color: black; height: 1em; width: 100%;"></div>	
Nemeth, J.	S214
Zavelson, L.	S214

**GSC**

Antinori, D. - GDT - SE Ofc.  
 Baumgardt, J. - GDT HQ, Indy  
 Blanchard, T. - GDT HQ, Indy  
 Harrold, M. - GDT - NE Ofc.  
 Hopper, P. - GDT - West  
 Neupert, J. - GDT HQ, Indy  
 Rieth, B. - GDT HQ, Indy  
 Sherman, M. - GDT HQ, Indy

Please forward questions regarding this distribution list to Linh Ho, ext. 53585



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HIGHLY CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER

ACS00686995

## 2ND GENERATION INTERVENTIONAL DEVICES

ACTUAL NUMBERS	Dec 1996	Jan 1997	Feb 1997	Mar 1997	Apr 1997	May 1997	Jun 1997	Jul 1997	Aug 1997	Sep 1997	Oct 1997	Nov 1997	Dec 1997
All	85%	86%	87%	87%	87%	87%	88%	89%	89%	87%	89%	87%	89%
SciMed/Mansfield	11%	12%	11%	11%	11%	11%	11%	9%	10%	12%	9%	11%	10%
IVT	1%	1%	0%	1%	1%	1%	1%	1%	1%	1%	1%	0%	0%
DVI	2%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	0%

## CORONARY STENT SHARE

ACTUAL NUMBERS	Dec 1996	Jan 1997	Feb 1997	Mar 1997	Apr 1997	May 1997	Jun 1997	Jul 1997	Aug 1997	Sep 1997	Oct 1997	Nov 1997	Dec 1997
ACS	88%	94%	92%	92%	94%	90%	80%	68%	65%	67%	31%	61%	64%
JJIS/Cordis													
Cook													
Medtronic													
AVE													
Schneider/Stiley													
Cook													
Cook													
ACS MULTILINK													
JJ PALMAZ-SCHATZ													
COOKGR2													
Wiktor													
MICRO STENT II													
WALLSTENT													
GR1&2													
GR1													

\* As of Aug 1997, the GR1 and GR2 were split.

## DIAGNOSTIC CATHETERS

ACTUAL NUMBERS	Dec 1996	Jan 1997	Feb 1997	Mar 1997	Apr 1997	May 1997	Jun 1997	Jul 1997	Aug 1997	Sep 1997	Oct 1997	Nov 1997	Dec 1997
Cordis/J&J													
SciMed/Mansfield													
USCI													
Medtronic													
Malincrodt													
Namco													
MediDyne													
Cook													
DAIG													
ACS													
Cordis Diagnostics	42%	42%	49%	31%	46%	48%	47%	48%	43%	42%	43%	41%	44%
SciMed Diagnostics	27%	27%	24%	48%	29%	27%	26%	30%	35%	32%	32%	35%	31%
USCI Diagnostics	25%	25%	22%	16%	19%	19%	18%	13%	11%	14%	12%	11%	12%
Medtronic Diagnostics	2%	2%	2%	1%	2%	1%	4%	5%	4%	5%	3%	6%	6%
Malincrodt Diagnostics	3%	3%	2%	2%	3%	3%	3%	2%	3%	3%	3%	3%	3%
Namco Diagnostics	1%	1%	0%	1%	0%	1%	1%	1%	1%	1%	1%	1%	1%
MediDyne Diagnostics	1%	1%	1%	0%	1%	0%	1%	1%	1%	1%	1%	0%	1%
Cook Diagnostics													
Daig Diagnostics													
ACS Diagnostics													

# EXHIBIT 5

# GUIDANT

# December 1998

**JAN 25 1999**

# U.S. Market Overview

## VASCULAR INTERVENTION

**C O N F I D E N T I A L**

## Distribution

### Senior Staff

Calfee, Richard	Houston
Graham, G.	S212
Johnson, G.	S121
Larson, B.	T500
Martlage, D.	S211
McInnes, P.	T520
Mead, D.	S232
Murray, M.	S220
Neels, G.	S112
Norton, S.	T200
Pandolfino, E.	S112
Peterson, T.	S214
Simpson, C.	S116

## Finance

Bartels, S.	S216
Koford, D.	T120

### **Business Development**

Cummings, C.	S214
Nemeth, J.	S214
Wallén, R.	S214
Zavelson, L.	S214

**Global Marketing**  
(80 copies)

### ***Directors***

Baer, P.	Houston
Bradshaw, T.	Houston
Chludzinski, M.	S238
Crall, C.	T540
Crapenhoft, M.	S214
Degois-Sainz, M.	S311
Edison, J.	Houston
Esselstein, B.	T120
Garfield, G.	S214
Hirsch, E.	S214
King, G.	GDT-Jpn
Kitchen, T.	S214
Lott, S.	Houston
Malito, O.	S116
Mondry, M.	S242
Muller, P.	S116
Nayak, V.	S120
Raggi, L.	S216
Saltman, B.	S135
Schneiderman, G.	S214
Sirhan, M.	S238
Spaulding, R.	S232
Thornton, R.	Houston

## Temocula

Winton, B.	T400
Kimes, R.	T520

**GSC**

Antinori, D. - GDT - SE Ofc.  
Baumgardt, J. - GDT HQ, Indy  
Blanchard, T. - GDT HQ, Indy  
Davis, B. - S001  
Ethridge, J. - S001  
Harrold, M. - GDT - NE Ofc.  
Hopper, P. - S112  
Neupert, J. - GDT HQ, Indy  
Rhatigan, K. - S001  
Rieth, A. - GDT HQ, Indy  
Sherman, M. - GDT HQ, Indy

**GDT HQ**

Garrett, M. - GDT HQ, Indy  
Harris, J. - GDT HQ, Indy  
Sherman, K. - GDT HQ, Indy

**GDT JPN**

Asano, K. - GDT JPN  
Heilbrunn, D. - GDT JPN  
Ito, K. - GDT JPN  
Miyashita, A. - GDT JPN  
Ohnishi, S. - GDT JPN  
Suzuki, K. - GDT JPN



**Please forward questions regarding this distribution list to Linh Ho, ext. 53585**

# AX-981

98-80-SLR

<http://group.vniisprache.uni-muenchen.de>

## 2ND GENERATION INTERVENTIONAL DEVICES

ACTUAL NUMBERS	Dec 1997	Jan 1998	Feb 1998	Mar 1998	Apr 1998	May 1998	Jun 1998	Jul 1998	Aug 1998	Sep 1998	Oct 1998	Nov 1998	Dec 1998
All	89%	87%	89%	91%	91%	92%	92%	91%	92%	92%	92%	92%	92%
BSX/SciMed/Schneider	10%	12%	10%	8%	9%	7%	7%	8%	8%	7%	8%	7%	7%
ROTABLATOR													
% of all devices (BDC + Alt. Tech.)	38%	38%	40%	40%	41%	42%	43%	43%	45%	46%	44%	45%	46%

## CORONARY STENT SHARE BY MANUFACTURER

ACTUAL NUMBERS	Dec 1997	Jan 1998	Feb 1998	Mar 1998	Apr 1998	May 1998	Jun 1998	Jul 1998	Aug 1998	Sep 1998	Oct 1998	Nov 1998	Dec 1998
ACS	64%	59%	54%	48%	47%	47%	44%	39%	35%	29%	30%	39%	49%
Boston Scientific	1%	18%	27%	34%	36%	39%	44%	5%	19%	34%	32%	33%	31%
AVE	23%	16%	14%	15%	15%	12%	10%	45%	35%	31%	32%	24%	16%
JJIS/Cordis	8%	5%	4%	3%	2%	2%	1%	9%	6%	5%	5%	4%	4%
Cook	3%	2%		1%	1%		1%	1%	1%	0%	1%	0%	0%
Medtronic													0%

## CORONARY STENT SHARE

ACTUAL NUMBERS	Dec 1997	Jan 1998	Feb 1998	Mar 1998	Apr 1998	May 1998	Jun 1998	Jul 1998	Aug 1998	Sep 1998	Oct 1998	Nov 1998	Dec 1998
BSX/SciMed/Schneider	64%	58%	53%	41%	3%	16%	32%	38%	35%	15%	23%	23%	43%
AVE					36%	34%	31%	27%	22%	29%	30%	22%	28%
ACS				10%	10%	10%	9%	8%	5%	17%	17%	10%	14%
JJIS/Cordis			7%	7%	11%	13%	14%	12%	12%	5%	5%	4%	4%
ACS			1%										
AVE	1%	18%	27%	34%	33%	23%	12%	12%	12%	12%	13%	6%	3%
BSX/SciMed/Schneider													
BSX/SciMed/Schneider													
JJIS/Cordis	23%	13%	7%	5%	5%	2%	1%	1%	1%	2%	2%	1%	1%
Medtronic	3%	2%		1%	1%	1%	1%	1%	1%	3%	4%	3%	2%
Cook	8%	5%	4%	3%	2%	2%	1%	1%	1%	16%	5%	1%	0%
GR2													0%
Wikt/Wiktor Rival													0%
NIR w/SOX													0%
Palmaz Shatz													0%
GR2													0%

As of Sept 98, the NIR Share was split to NIR and NIR w/SOX

## ACS CORONARY STENT AVERAGE DAILY SALES (DOMESTIC)

	Dec-97	Jan-98	Feb-98	Mar-98	Apr-98	May-98	Jun-98	Jul-98	Aug-98	Sep-98	Oct-98	Nov-98	Dec-98
ACS Multi-Link Duet	1,864	1,484	1,210	1,071	980	982	825	716	566	447	371	938	1690
ACS Multi-Link	51,333	51,333	258	361	447	480	442	420	423	435	434	239	40
ACS Multi-Link HP													
Total ACS Coronary Stents	1,864	1,535	1,469	1,432	1,428	1,462	1,268	1,136	988	882	805	1,177	1,760